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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/517,402

12/07/2004

Christopher J. Criscuolo

2832 (203-3308)

4034

7590

06/16/2006

Lisa J Moyles
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EXAMINER

ANDERSEN, MICHAEL T

ART UNIT

PAPER NUMBER

3734

DATE MAILED: 06/16/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/517,402	Applicant(s) CRISCUOLO ET AL.	
	Examiner M. Thomas Andersen	Art Unit 3734	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 December 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 21-31 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 21-31 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 07 December 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>12/7/04, 3/29/05</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Priority

Acknowledgement is made of the claim to benefit of provisional application number 60/388,119, filed on 06/11/2002.

Information Disclosure Statement

The information disclosure statements (IDS) received on 12/07/2004 and 03/29/2005 are acknowledged. The submissions are in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statements are being considered by the examiner.

Specification

The disclosure is objected to because of the following minor informalities: page 3, line 5, "hold" should read "hole" ; page 4, line 8, "on the border" should likely read "on the order" ; page 10, line 12, "114" should likely read "110" ; page 11, line 2, "reengagement" should likely read "reengagement of".

Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

102(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims **21-24**, and **27** rejected under 35 U.S.C. **102(b)** as anticipated by **Huebner**, U.S. Patent No. **6,030,162**.

Claim 21: Huebner's figure 1 shows a surgical tack comprising a head 26 having a drive thread formed on an outer surface thereof; a barrel portion 28 extending from the head and having a tissue engaging thread formed on an outer surface thereof; and a throughbore (figure 3) extending through the head and barrel portion for receipt of a drive tool.

Claim 22: Due to the different diameters of the thread on the head portion 26 and the barrel portion 28, the two threads are discontinuous (better seen in figure 3, or figure 21).

Claim 23: Again, because of the different diameters of the head portion 26 and the barrel portion 28, there can be said to be a transition zone between the drive thread and the tissue engaging thread.

Claim 24: Huebner discloses, "The trailing section threads [the drive threads on the head] may be of constant diameter *or may taper outwardly toward the trailing end.*" Huebner, col. 4, lines 35-36, emphasis added. Thus, the leading edge of the drive thread can be said to be tapered.

Claim 27: Huebner's figure 1 shows that the maximum diameter of the drive thread 26 is greater than the maximum diameter of the tissue engaging thread 28.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim **26** is rejected under 35 U.S.C. **103(a)** as being unpatentable over **Huebner**.

Claim **26**: Huebner does not appear to expressly disclose a chamfered drive thread on the head portion 26. However, Huebner does disclose a chamfer 80 on the leading section 24 (See Huebner figure 2; Huebner, col. 4, 63-65). Huebner also discloses, “[the] termination zone 80 [or chamfered portion] could be used on any of the screws described herein.” Huebner, col. 5, lines 6-7. This implies that the chamfered portion can be used on the trailing head portion 26. It would be obvious to apply a chamfered portion on the head portion 26 so as to allow for smooth rotation through and insertion into shaft 146.

Claims **25** and **28** are rejected under 35 U.S.C. **103(a)** as being unpatentable over **Huebner**, as applied to claims **21-24** and **26-27** above, in view of **Muhling**, U.S. Patent No. **5,169,400**. Huebner discloses a throughbore but not a throughbore that has a D-shaped cross-section. Muhling claims in claim 1 “a bone screw . . . comprising an externally threaded shaft in which a tool insertion channel [or throughbore] open at the top . . . the cross-section of said insertion channel being non-circular and corresponding to the cross-section of a tool used for screwing-in said screw . . .” Muhling, claim 1. Muhling’s figures 2-5 disclose a number of different throughbore shapes. The point of Muhling’s invention is to better allow torque to be applied by the insertion tool to the screw. A D-shaped throughbore is considered within the scope of Muhling’s invention, due to the following language in claim 1, “the cross-section of said insertion channel being non-circular and corresponding to the cross-section of a tool used for screwing-in

said screw.” Id. It would be obvious to combine Muhling with Huebner because they involve the same field of endeavor and modifying the through-bore to be D-shaped would better allow torque to be applied to the screw, as explained by Muhling.

Claims **29-30** are rejected under 35 U.S.C. **103(a)** as being unpatentable over **Simon**, U.S. Patent No. **5,891,146**, in view of **Muhling**, U.S. Patent No. **5,169,400**.

Simon discloses a wedge orthopedic screw that has a head (top portion), a tapered barrel portion (figures 1-2) having a tissue engaging thread formed on the outer surface thereof; and a bore extending through the head and the tapered barrel portion. Simon, however, does not expressly disclose a bore having a non-circular cross-section. As explained above, Muhling discloses a bore having a non-circular cross-section, interpreted to include a D-shaped bore. It would be obvious to combine Simon with Muhling for the same reasons it would be obvious to combine Huebner with Muhling – to better allow torque to be applied to the screw.

Claim **31** is rejected under 35 U.S.C. **103(a)** as being unpatentable over **Huebner**, in view of **Simon**, and further in view of **Muhling**. All of these references involve the same field of endeavor and are related to screws. As mentioned above, Huebner discloses a screw having a head portion with a drive thread formed on an outer surface thereof, a barrel portion having a tissue engaging thread formed on an outer surface thereof, the tissue engaging thread being discontinuous from the drive thread; and a bore extending through the head and the tapered barrel portion. Huebner does disclose that the barrel portion can be tapered, as the thread diameter grows increasingly larger in the distal portion numbered 24. However, Simon more expressly

Art Unit: 3734

discloses a tapering barrel portion that can progressively grab the tissue or bone to which it is applied. It would be obvious to modify Huebner to have more of a tapered barrel portion so as to lessen the invasiveness of inserting a screw into tissue.

As described above, it also would be obvious to use a non-circular throughbore as described by Muhling.

Conclusion

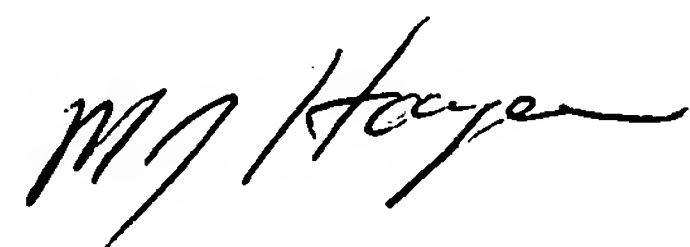
Any inquiry concerning this communication or earlier communications from the examiner should be directed to M. Thomas Andersen whose telephone number is (571) 272-8024. The examiner can normally be reached on M-F 8AM-4:30PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hayes can be reached on (571) 272-4959. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

M. Thomas Andersen

June 12, 2006



**MICHAEL J. HAYES
SUPERVISORY PATENT EXAMINER**